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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/579,327	05/25/00	RIORDAN	N RIORD.004A

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HM12/0424

EXAMINER	
FIELDS, I	
ART UNIT	PAPER NUMBER
1645	7

DATE MAILED: 04/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/579,327	RIORDAN ET AL.	
	Examiner	Art Unit	
	Iesha P Fields	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-21 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restriction

Applicant's election without traverse of Group I in Paper No. 6 is acknowledged.

Claim Rejections - 35 USC § 112

1. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-14 are vague and indefinite in recitation of a physiologically "acceptable pH". One of skill in the art would be unable to determine the meets and bounds of such a limitation. For instance is an acceptable pH 2, 7, 8 etc.? Without a clear definition as to what constitutes an "acceptable pH " one of skill in the art would be unable to replicate the claim.

2. Claims 1, 13, 16, and 21 are vague and indefinite in recitation of the term "TCA". Applicant's can overcome the rejection by amending the claims to recite "Trichloroacetic Acid".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

2. Claims 1-4, 6, 8-9, and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuzaki et al.

The claims are drawn to a method of making a peptidoglycan extract from bacteria.

Matsuzaki et al. (US Patent 5.601,999) disclose a method of making a peptidoglycan extract from bacteria. Matsuzaki et al. further disclose that the method may be used in making extracts from several species of *Lactobacillus* including *Lactobacillus fermentum* (See Detailed Description of the Invention; Column 2 lines 14-15). Matsuzaki et al. further disclose that the extraction method comprises centrifugation, lyophillization and treating heated bacteria with hydrochloric acid.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 11-12, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matasuzaki et al. further in view of Converse et al.

The claims are drawn to a method of making a peptidoglycan extract from bacteria comprising the removal of lipids.

Matasuzaki et al. does not teach of a method of making a peptidoglycan extract from bacteria comprising the removal of lipids.

Converse et al. (Lipoprotein analysis 1992 IRL Press at Oxford University Press, pages 232-34) teach of a method of lipid extraction. Converse et al. further teach of a method of removing lipids using chloroform.

Given that 1) Matsuzaki et al. has taught of a method of making a peptidoglycan extract from *Lactobacillus fermentum* and that 2) Converse et al. has taught of a method of extracting lipids it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to remove as cell wall components including lipids from the peptidoglycan extract. One would have been motivated to remove the lipids because in removing the lipids from the solution one would reasonably expect to obtain a more pure sample. In view of the teachings of Matsuzaki et al. that the peptidoglycan extract is an antitumor agent, a more pure sample would be expected to have a greater antitumor effect.

4. Claims 1, 4-5, 7, 10, 13, 15-17, and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuzaki and Converse et al. in view of Roe et al.

The claims are drawn to a method of making a peptidoglycan extract from bacteria comprising heat treatment, ultrafiltration, and treatment with acetic acid.

The teachings of Matsuzaki and Converse et al. are set forth above.

Matsuzaki and Converse et al. do not teach of a method of making a peptidoglycan extract from bacteria comprising heat treatment, ultrafiltration, and treatment with acetic acid.

Roe et al. (Protein Purification Methods, Oxford ; New York : IRL Press at Oxford University Press, 2nd ed., pages 112-116 and 141-43) teach of standard techniques used in protein purification. The standard techniques include heat treatment (i.e. high temperatures), denaturation by extremes of pH and treatment with strong acids such as acetic acid and TCA. (See especially sections 66.1-66.3). Roe et al. further teach of several filtration methods (See especially chapter 3).

Given that 1) Matsuzaki et al. has taught of a method of making a peptidoglycan extract from *Lactobacillus fermentum* and that 2) Converse et al. has taught of a method of extracting lipids from a solution and that 3) Roe et al. has taught of standard techniques used in protein purification it would have been *prima facie* obvious to

one of ordinary skill in the art at the time of the invention to make a peptidoglycan extract from bacteria employing standard purification techniques. One would have been motivated to employ techniques such as heat treatment, ultrafiltration, and treatment with a strong acid because such techniques are well known purification techniques.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iesha P Fields whose telephone number is (703) 605-1208. The examiner can normally be reached on 7am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Iesha Fields

April 23, 2001

MARK NAVARRO
PRIMARY EXAMINER